

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TRANSWORLD HEALTHCARE, INC.**

I. PREAMBLE

Transworld Healthcare, Inc. hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by Transworld Healthcare, Inc., and all of its subsidiaries that submit claims for reimbursement to any Federal health care program (as defined below) (collectively, "Transworld"), and Covered Persons (as defined below) with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"). This CIA shall not apply to The PromptCare Companies, Inc. and SteriPharm, Inc. unless and until any operations of The PromptCare Companies, Inc. and/or SteriPharm, Inc. are combined with the operations of Transworld, or The PromptCare Companies, Inc. and/or SteriPharm, Inc. assume functions currently performed by Transworld. Transworld's compliance with the terms and conditions in this CIA shall constitute an element of Transworld's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Transworld Healthcare, Inc. is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Transworld represents that prior to the execution of this CIA, Transworld voluntarily established a Corporate Compliance Program which provides, *inter alia*, for a Corporate Compliance Officer, a compliance training and education program, a confidential reporting hotline, a screening methodology for prospective employees, and which includes various policies and procedures aimed at ensuring that Transworld's participation in the Federal health care programs conforms to all applicable statutes, regulations and other legal requirements contained in any formal program directives issued by appropriate governmental agencies, *e.g.*, the Health Care Financing Administration ("HCFA") and/or their contractors (collectively, the "Legal Requirements"). With respect to the Legal Requirements, nothing in this CIA is intended to limit or expand Transworld's right to seek clarification and/or challenge any

governmental interpretation or application of a statute, regulation, manual provision, or other governmental issuance to durable medical equipment suppliers generally or to Transworld's operations in particular, however, any such seeking of clarification or challenge does not affect Transworld's obligation to comply with the terms of this CIA and with all Legal Requirements.

Pursuant to this CIA, Transworld agrees to operate its Corporate Compliance Program consistent with the requirements of this CIA and to adopt or modify any components of Transworld's existing Corporate Compliance Program in order to be in compliance with all of the corporate integrity obligations under this CIA.

For purposes of this CIA, the term "Covered Persons" includes any of Transworld's employees; and its contractors or agents who have any responsibility for or involvement with Transworld's operations relating to the provision, marketing, ordering or billing of covered health care items and services furnished to Federal health care program beneficiaries and reimbursable by the Federal health care programs ("Items and Services").

II. TERM OF THE CIA

The period of the compliance obligations assumed by Transworld under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the latter of the date on which the final signatory executes this CIA or the date on which the final signatory executes the related Settlement Agreement (the "Effective Date").

III. CORPORATE INTEGRITY OBLIGATIONS

Transworld shall comply with the following corporate integrity obligations and shall ensure that the obligations specified below are incorporated into its existing Corporate Compliance Program:

A. Compliance Officer and Compliance Committee

1. *Compliance Officer.* Transworld represents that it has appointed a Compliance Officer. Transworld shall ensure that the Compliance Officer will provide regular (at least quarterly) reports regarding compliance matters directly to the CEO, President, and/or the Board of Directors of Transworld, and shall be authorized to report to the Board of Directors (or the audit committee thereof) at any time. Further, the Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer also shall be responsible for monitoring the day-to-day activities engaged in by Transworld to further its compliance objectives as well as for any reporting

obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, Transworld shall notify OIG, in writing, within fifteen (15) days of such a change.

2. *Compliance Committee.* Within 120 days after the Effective Date of this CIA, Transworld shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and management representatives representing the individual Transworld operating subsidiaries (e.g., representatives from each major department, such as billing, clinical, human resources, audit, and operations) and one senior representative of Transworld Healthcare, Inc. The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards

1. *Code of Conduct.* Transworld represents that it has developed a Code of Conduct which reflects its commitment to ethical conduct in all of its affairs, including compliance with all Legal Requirements. Within 120 days of the Effective Date of this CIA, Transworld shall amend its Code of Conduct so that it meets the requirements set forth in this Section, and shall ensure that its Code of Conduct is distributed to all Covered Persons. Transworld shall ensure that the promotion of, and adherence to, the Code of Conduct is an element in evaluating the performance of managers, supervisors, and all other Covered Persons. The Code of Conduct shall, at a minimum, include the following elements:

- a. Transworld's commitment to full compliance with Legal Requirements, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by appropriate regulatory agencies, e.g., HCFA, and/or their agents;
- b. Transworld's requirement that all of its Covered Persons shall be expected to comply with all Legal Requirements and with Transworld's own Policies and Procedures (including the requirements of this CIA);
- c. the requirement that all of Transworld's Covered Persons shall be expected to report suspected violations of any Legal Requirements or of Transworld's own Policies and Procedures;
- d. the possible consequences to both Transworld and Covered Persons of failure to comply with all Legal Requirements and with Transworld's own Policies and Procedures or of failure to report such non-compliance; and

- e. the right of all Covered Persons to use the Confidential Disclosure Program (as described in Section III.H.), as well as Transworld's commitment to confidentiality and non-retaliation with respect to all such disclosures made through this program.

Transworld will annually review the Code of Conduct and will make any necessary revisions to ensure compliance with the Legal Requirements and with this CIA. These revisions shall be distributed to Covered Persons within 30 days of implementing such a change. Covered Persons shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Policies and Procedures.* Within 120 days of the Effective Date of this CIA, Transworld shall ensure that it has developed and implemented written policies and procedures regarding the operation of Transworld's compliance program and its compliance with all Legal Requirements ("Policies and Procedures"). The Policies and Procedures shall include disciplinary guidelines and methods for individuals to make disclosures or otherwise report on compliance issues to Transworld management through Transworld's Confidential Disclosure Program (described in Section III.H.). Additionally, Transworld shall ensure that such Policies and Procedures address business arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries, in violation of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) or 42 U.S.C. § 1395nn (the "Stark Law"), and such Policies and Procedures shall incorporate the requirements set forth in Sections III.D and III.E.

The Policies and Procedures shall include a process for the collection of coinsurance (co-payment and deductible amounts) consistent with applicable Legal Requirements. Transworld shall track the collection of coinsurance for all Medicare beneficiaries. On an annual basis, Transworld shall review its practices regarding collection of coinsurance, and Transworld shall include in its annual reports to the OIG: (1) a report on the operation of the coinsurance collection process; (2) the amounts of coinsurance for Medicare beneficiaries (a) due on all claims (prior to billing), (b) billed (to insurers and/or beneficiaries), and (c) collected; and (3) a report summarizing the reasons for uncollected coinsurance amounts and the efforts of Transworld to collect such amounts.

Transworld shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. For the purposes of compliance with this CIA, once HCFA, a HCFA agent, and/or the OIG has issued a guidance or clarification to Transworld specifically or to the durable medical equipment supplier community generally, if such guidance requires modification of Transworld's Policies and Procedures, then Transworld shall be permitted a reasonable period of time, up to 90 days, to bring its Policies and Procedures into accord with any such HCFA, HCFA agent,

or OIG guidance or clarification. This 90-day period to amend Transworld's Policies and Procedures shall not affect Transworld's obligation to submit claims in accordance, and otherwise comply, with such guidance or clarification upon the effective date of the guidance or clarification, nor shall it affect the effective date of such guidance or clarification for Federal health care program purposes. A copy of the Policies and Procedures will be provided to OIG in the Implementation Report. Throughout the term of this CIA, the Policies and Procedures shall also be available to OIG upon request.

Within 120 days after the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate Covered Persons. Compliance staff or supervisors should be available to explain any and all Policies and Procedures.

C. Training and Education

1. *General Training.* Within 120 days of the Effective Date of this CIA, Transworld shall provide at least two (2) hours of general training to each Covered Person (the "General Training"). This General Training may be provided in a group setting and shall explain Transworld's:

- a. Corporate Integrity Agreement requirements;
- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
- c. Code of Conduct.

In connection with the General Training, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by Transworld's Code of Conduct. Individuals who newly meet the definition of Covered Person shall receive the General Training and shall complete the required certification within one (1) month after becoming a Covered Person or within 120 days of the Effective Date of this CIA, whichever is later. Each Covered Person shall receive such General Training on an annual basis. All training materials used for the General Training shall be made available to OIG upon request.

2. *Billing Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is involved directly or indirectly in the preparation or submission of reimbursement claims (including, but not limited to, coding and billing) for Items and Services ("Billing Personnel") shall receive at least three (3) hours of billing training (the "Billing Training") in addition to the General Training required above. This Billing Training may be provided in a group setting and shall include a discussion of:

- a. the relevant portions of the Policies and Procedures and the Legal Requirements for the submission of claims to Federal health care

programs for Items and Supplies furnished to beneficiaries of such programs;

b. the Policies and Procedures and Legal Requirements applicable to medical record documentation;

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

d. the legal sanctions for improper billings; and

e. examples of proper and improper billing practices.

Individuals who newly meet the definition of Billing Personnel shall receive the Billing Training set forth above within one (1) month after becoming a Billing Personnel or within 120 days of the Effective Date of this CIA, whichever is later. If a new Billing Personnel has any responsibility for the preparation or submission of claims and/or the assignment of billing codes prior to completing this Billing Training, a Transworld employee, contractor or agent who has completed the Billing Training shall review all of such Billing Personnel's work regarding submission of claims and the assignment of billing codes. Each Billing Personnel shall receive the Billing Training on an annual basis.

All Billing Training Materials shall be made available to OIG, upon request. Persons providing the Billing Training shall be knowledgeable with respect to the areas listed above.

3. *Sales Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is involved directly or indirectly in the sales or marketing of Items and Services ("Sales Personnel") shall receive at least three (3) hours of training in addition to the General Training required above (the "Sales Training"). The Sales Training may be provided in a group setting and shall include a discussion of:

- a. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes;
- b. policies, procedures and other requirements applicable to the Federal health care program requirements of medical necessity and Certificates of Medical Necessity;
- c. the personal obligation of each individual involved in the billing process to make appropriate and accurate representations regarding coverage and billing for Items and Services;

- d. applicable Legal Requirements;
- e. the legal sanctions for improper sales or marketing strategies or arrangements; and
- f. examples of proper and improper marketing strategies or arrangements.

Individuals who newly meet the definition of Sales Personnel shall receive the Sales Training set forth above within one (1) month after becoming a Sales Personnel or within 120 days of the Effective Date of this CIA, whichever is later. If a new Sales Personnel has any responsibility for the sales or marketing of Items or Supplies prior to completing the Sales Training set forth above, a Transworld employee, contractor or agent who has completed the Sales Training shall review all of such Sales Personnel's work regarding the sales and marketing of Items and Services, until the required training has been completed. Each Sales Personnel shall receive the Sales Training on an annual basis.

All Sales Training materials shall be made available to OIG, upon request. Persons providing the Sales Training must be knowledgeable with respect to the areas listed above.

4. *Certification.* Each individual who is required to attend any of the training requirements set forth above in this Section III.C. shall certify, in writing, that he or she in fact has attended and has received the required training.

The Compliance Officer shall retain the certifications, along with specific course materials. In addition, the Compliance Officer shall also retain the Code of Conduct certifications as required in conjunction with the General Training. All certifications shall be made available to OIG upon request.

D. Contracts for Marketing and Sales Related Services

Transworld will continue, and amend as necessary, its policies reasonably designed to prevent contractual arrangements with referral sources and recipients of referrals from violating the Anti-Kickback Statute and the Stark Law, and will implement procedures to evaluate all existing contractual relationships with contractors, vendors, and agents to the extent not already so evaluated. At a minimum, Transworld shall ensure that all independent contractor agreements with parties in a position to refer or recommend Federal health care program beneficiaries to Transworld for the purchasing, leasing, or ordering of any item or service, facility or service for which payment may be made in whole or in part from a Federal health care program, under which such parties are to provide marketing or sales-related services to Transworld, meet the following requirements:

1. The agreement shall be in writing and signed by the parties;
2. The agreement shall specify the services to be provided by the independent contractor to Transworld;
3. The compensation rate, which may be based on hours worked or other service-based criteria, paid to the independent contractor shall be set in advance, be consistent with fair market value in an arms length transaction, and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program;
4. The terms of the agreement shall specify that the compensation rate shall apply for a period of one (1) year from the effective date of the agreement, and may be renegotiated by the parties only at the expiration of that one year period;
5. The aggregate services contracted for shall not exceed those which are reasonably necessary to accomplish the commercially reasonable business purposes of the services;
6. The services performed under the agreement shall not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law;
7. The contract shall include a provision that the individual independent contractor shall comply with Transworld's Corporate Compliance Program which includes training related to the Anti-Kickback Statute and the Stark Law; and
8. The independent contractor shall be required to certify, at the time of signing the agreement and semi-annually thereafter, that the independent contractor:
 - a. does not have a Medicare Part B provider or supplier number;
 - b. does not have a financial relationship with any individual or entity, other than Transworld, that has a Medicare Part B provider or supplier number where that individual or entity refers business to Transworld; and
 - c. is not an immediate family member or member of the household (as defined by 42 U.S.C. § 1320a-7(j)) of any individual who has a Medicare Part B provider or supplier

number where that individual, or an entity owned or controlled by that individual, refers business to Transworld;

9. The independent contractor shall be required to notify Transworld prior to a change in circumstances under which the contractor could not truthfully certify the above facts for any time period during which the contract is in effect; and
10. The independent contractor shall be required to certify, at the time of signing the agreement, that the contractor shall comply with Transworld's Corporate Compliance Program and with the Anti-Kickback Statute and the Stark Law.

Transworld shall provide to OIG, upon request, copies of all personal services and management contracts subject to this Section III.D, and, to the extent available, all non-privileged communications related to the contracts and the actual performance of the duties under the contracts such as time sheets, service logs, and payment documentation (e.g., Form 1099s and record of checks/wire transfers).

E. Commission Sales Employees

Transworld shall institute a policy or policies reasonably designed to ensure that each of its agreements with sales or marketing employees ("Commission Sales Employee(s)") are not in violation of the Anti-Kickback Statute. At a minimum, Transworld shall ensure that its relationships and agreements with Commission Sales Employees are structured to meet the following requirements:

1. For each Commission Sales Employee:
 - a. Transworld issues a W-2;
 - b. Transworld withholds the Commission Sales Employee's federal unemployment taxes (FUTA);
 - c. Transworld pays the Commission Sales Employee's Social Security taxes (FICA);
 - d. The Commission Sales Employee is eligible to participate in or receive employee benefits pursuant to Transworld's employee benefit plans;
 - e. Transworld makes reimbursement available to the Commission Sales Employees for travel and other reasonable business expenses;

- f. Transworld trains the Commission Sales Employee with respect to the uses and characteristics of the product that the Commission Sales Employee sells and with respect to sales and marketing methodologies;
 - g. The Commission Sales Employee personally renders the services for which the Commission Sales Employee is employed, except for delegation to other Transworld employees;
 - h. The Commission Sales Employee reports to a supervisor or manager on a regular and ongoing basis; and
 - i. The Commission Sales Employee has the right to end his or her employment with Transworld at any time without penalty for ending his or her employment, except as such penalties may relate to employment provisions regarding covenants not to compete.
- 2. Each Commission Sales Employee shall certify, in writing, that he or she understands and agrees that:
 - a. a failure to meet any of the requirements in this section III.E shall be grounds for termination of employment of that Commission Sales Employee;
 - b. where the Commission Sales Employee promotes items or services other than those of Transworld, any discount or reduction in price of any such other item or service will not be conditioned on the purchase or lease of any Items or Services offered by Transworld which are promoted by the Commission Sales Employee;
 - c. the Commission Sales Employee shall comply with Transworld's Corporate Compliance Program, which includes training related to the Anti-Kickback Statute and Stark Law;
- 3. The sales or marketing of any Items or Services offered by Transworld and marketed by any Commission Sales Employee shall not include the direct offer, promotion, sale or lease to any Federal health care program beneficiary as specifically set forth in 42 U.S.C. § 1395m(a)(17);
- 4. Each Commission Sales Employee shall be required to obtain prior approval by the Compliance Officer before giving any gift of value

exceeding \$50.00, and before giving more than two gifts in any one year, to any individual or entity that is a possible referral source to Transworld;

5. Each Commission Sales Employee shall certify, in writing, that he or she:
 - a. does not have a Medicare Part B provider or supplier number;
 - b. does not have a financial relationship with any individual or entity, other than Transworld, that has a Medicare Part B provider or supplier number where that individual or entity refers business to Transworld; and
 - c. is not an immediate family member or member of the household (as defined by 42 U.S.C. § 1320a-7(j)) of any individual who has a Medicare Part B provider or supplier number where that individual, or an entity owned or controlled by that individual, refers business to Transworld; and
6. Each Commission Sales Employee shall be required to notify Transworld prior to a change in circumstances under which the employee could not truthfully certify the above facts.

If a Commission Sales Employee fails to meet any of these standards, Transworld shall notify such employee of such failure and Transworld shall attempt to cure such failure within 30 days. In the event the Commission Sales Employee has not cured any such breach within the 30-day period, Transworld shall terminate the employment of that Commission Sales Employee. All documents relating the failure of any Commission Sales Employee to meet any of the above standards shall be made available to the OIG upon request. Transworld shall report the failure of any Commission Sales Employee to meet any of the above standards, as well as the action taken by Transworld in response to such failure, to the OIG in Transworld's Annual Report. The above standards for a Commission Sales Employee are intended to set forth Transworld's obligations under this CIA only, and do not affect or require evaluation by the Legal Reviewer (as described in Section III.F.1, below) of Transworld's potential liability under the Anti-Kickback Statute and other Legal Requirements applicable to such relationships.

F. Review Procedures

1. Legal Review. Prior to the first anniversary of the execution of this CIA, and annually thereafter, Transworld shall retain an independent, experienced attorney or law firm with knowledge of the Legal Requirements ("Legal Reviewer") to review all

applicable independent contractor agreements and employment agreements or relationships with Commission Sales Employees that fall within the scope of Sections III.D or III.E to evaluate whether such agreements and relationships meet the applicable requirements and standards set forth in Sections III.D and III.E. These reviews shall be performed annually and cover each of the one-year periods beginning on the Effective Date of this CIA or the anniversary of that date. The Legal Reviewer shall certify that the review required under this section has occurred and shall provide a summary of its reviews to Transworld. Transworld will make available to the OIG the agreements and policies that have been reviewed pursuant to this section upon request. Transworld shall retain all agreements and policies that have been reviewed as well as all written reports generated by the Legal Reviewer relating to these reviews, and such reports shall be provided to the OIG with Transworld's Annual Reports.

2. *Prospective Claims Review.* Transworld represents that it has developed a series of internal compliance mechanisms to ensure that all claims for Items and Services submitted by Transworld to any Federal health care program meet all applicable Legal Requirements known to Transworld based upon reasonable inquiry. For the purposes of this Section III.F.2, "reasonable inquiry" shall include, at a minimum, review of all applicable statutes, regulations and program directives issued by appropriate government agencies and their contractors. Transworld will conduct the following review (the "Prospective Claims Review") of each claim for Items or Services prior to submitting such claim to any Federal health care program:

- a. Transworld's New Patient Registration Department, or its equivalent, shall verify that all verbal orders for Items or Services received from physicians meet applicable Legal Requirements known to Transworld based upon reasonable inquiry before Transworld furnishes the Items or Services ordered to the Federal health care program beneficiary or patient. The New Patient Registration Department, or its equivalent, shall provide the ordering physician with a written order form, and/or a certificate of medical necessity ("CMN") as appropriate, for completion;
- b. Transworld's CMN Department, or its equivalent, shall review the written order and/or CMN, and verify that: (1) the written order and/or CMN is consistent with any prior verbal order(s) received from the ordering physician; (2) such written order and/or CMN meets applicable Legal Requirements known to Transworld based upon reasonable inquiry; and (3) the written order and/or CMN is accurately completed by the ordering physician;

- c. Transworld's Billing Department shall verify that: (1) the written order or CMN exists for every Item or Service furnished to a Federal health care program beneficiary; (2) the shipping records confirm the quantity, type, and frequency of the Items and Services delivered to the Federal health care program beneficiary as requested by the ordering physician; and (3) based upon the Items and Services ordered by the physician, the written order or CMN, the Items and Services furnished by Transworld, the diagnosis of the specific beneficiary, and any other relevant information, the applicable Federal health care program claim form (e.g., HCFA 1500) is accurately completed, and is in compliance with the Legal Requirements known to Transworld based upon reasonable inquiry for that claim.

Transworld shall not submit any claim to any Federal health care program for which it is not able to verify the matters described in a, b, and c, above.

3. *Retrospective Claims Review.* Transworld shall designate one or more billing compliance auditors (the "Billing Compliance Auditors") to conduct quarterly retrospective reviews of claims submitted by Transworld to the Medicare program (the "Retrospective Claims Reviews"). Each Billing Compliance Auditor must have expertise in the billing, coding, reporting, and other requirements of the Medicare program.

The Retrospective Claims Reviews shall be performed quarterly and cover each calendar quarter, beginning with the calendar quarter that begins on July 1, 2000, through the expiration of the term of this CIA. The universe of each Retrospective Claims Review shall be all claims submitted to and paid by Medicare by the thirtieth day after the end of the calendar quarter under review. Each quarterly Retrospective Claims Review shall be completed within 90 days of the end of the calendar quarter under review. Each Retrospective Claims Review shall consist of a review of a sample of claims for Items or Services submitted by Transworld to the Medicare program during the relevant quarter covered by the review, and shall be performed in accordance with the following:

- a. Transworld's Billing Department shall categorize by product line (e.g., diabetic items and supplies, ostomy, and respiratory drugs) each Medicare beneficiary who received Items or Services from Transworld during the quarter under review, and for whom at least one claim was submitted to and paid by Medicare within the thirtieth day after the end of the calendar quarter under review, so that each beneficiary is included in each product line from which he or she received Items or

Services and for which claims were submitted to and paid by Medicare. Every Medicare beneficiary for whom a claim was submitted to and paid by Medicare must be included in at least one product line.

- b. Transworld shall use random number sampling to select a minimum of 25 beneficiaries from each product line. To generate the random product line samples of beneficiaries, Transworld shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/oig/oas/ratstat.html."
- c. For each product line sample of beneficiaries, the Billing Compliance Auditors shall request from the Billing Department the complete patient files for each beneficiary in the sample relating to that product line, as well as any other documentation reflecting the Items and Services furnished by Transworld to such beneficiaries.
- d. For each product line sample of beneficiaries, the Billing Compliance Auditors shall review all claims submitted by Transworld to the Medicare program for Items or Services related to that product line furnished to each beneficiary in the sample to verify the following:
 - i. Written physician orders, and CMNs where required, had been received and accurately completed by the ordering physician prior to the submission of any claim to the Medicare program for any Items or Services so ordered;
 - ii. All written physician orders and CMNs were consistent with any verbal orders received by Transworld from the ordering physician;
 - iii. Each beneficiary who received Items or Services from Transworld met the medical coverage, utilization, documentation, delivery, and other applicable Legal Requirements for the Medicare program (nothing in this section requires review of coinsurance collection efforts);

- iv. All Items and Services furnished to each beneficiary conformed with the quantity, type, and frequency requested by the ordering physician;
 - v. Each Medicare claim form (*e.g.*, HCFA 1500) submitted for Items or Services furnished to each beneficiary had been accurately completed, and is in compliance with the Legal Requirements for that claim, based upon the Items and Services ordered by the physician, the written order or CMN, the Items and Services furnished by Transworld, the diagnosis of the specific beneficiary, and any other relevant information;
 - vi. Where Items or Services sent to the beneficiary were returned to Transworld, Transworld either did not submit a claim for such Items or Services to the Medicare program, or Transworld promptly repaid or otherwise credited the Medicare program any monetary amount received by Transworld as reimbursement for the returned Items or Services; and
 - vii. The amount of reimbursement received by Transworld for each Item or Service furnished to the beneficiary was correct and payable in accordance with all applicable Medicare Legal Requirements (nothing in this section requires review of coinsurance collection efforts).
- e. For each claim for which the Billing Compliance Auditors are unable to verify each of the items set forth above, the Billing Compliance Auditors shall determine the amount of overpayment (as that term is defined in Section III.J) received by Transworld in association with that claim.

Transworld shall provide the OIG with a report of each Retrospective Claims Review (the "Retrospective Claims Review Report") for each product line. Each Retrospective Claims Review Report shall include the following:

- a. The Billing Compliance Auditors' findings regarding whether Transworld is submitting accurate claims for services billed to the Medicare program;

- b. The total dollar amount received by Transworld for all claims submitted to the Medicare program for Items and Services furnished to the beneficiaries in the sample during the quarter under review;
- c. The total dollar amount of all overpayments received by Transworld and identified by the Retrospective Claims Review.

Transworld shall retain an entity, such as an accounting, auditing, or consulting firm (hereafter "Independent Review Organization"), to review whether Transworld has performed the Retrospective Claims Reviews in conformance with the agreed-upon procedures as described above. The Independent Review Organization must have expertise in the billing, coding, reporting, and other requirements of the Medicare program. Transworld shall require the Independent Review Organization to produce reports on its findings.

A complete copy of each Retrospective Claims Review Report and the Independent Review Organization's report of findings regarding such Retrospective Claims Review Report, shall be submitted with Transworld's Annual Report to the OIG for the year which includes the quarter covered by that Retrospective Claims Review. All documents relating to the Retrospective Claims Reviews, and the Independent Review Organization's reviews, shall be retained by Transworld for the duration of this CIA, and shall be furnished to the OIG upon request.

Based on the results of previous Retrospective Claims Reviews performed in accordance with this CIA, after a minimum of three quarterly Retrospective Claims Review Reports have been provided to OIG, OIG may, at its sole discretion and for subsequent quarters of this CIA, reduce or dismiss Transworld's obligation to retain an Independent Review Organization to review whether Transworld has performed the Retrospective Claims Reviews in conformance with the agreed-upon procedures as described above.

4. *Compliance Review.* Transworld shall also retain an Independent Review Organization to perform review procedures to assist Transworld in assessing the adequacy of its compliance practices pursuant to this CIA (the "Compliance Review"). The Compliance Review shall cover the one-year period beginning on the Effective Date of this CIA. The Independent Review Organization must be retained to conduct the Compliance Review for the first year within 120 days of the Effective Date of this CIA.

The Compliance Review shall include section by section findings regarding the requirements of this CIA, and shall provide findings regarding whether Transworld's program, policies, procedures, and operations comply with the terms of this CIA.

The Independent Review Organization shall generate a report of its findings related to the Compliance Review (the "Compliance Review Report") and a complete copy of the Compliance Review Report shall be included in Transworld's first Annual Report to OIG.

G. Verification and Validation

In the event the OIG has reason to believe Transworld's Legal Review or Retrospective Claims Review fails to conform to the requirements of this CIA or indicates an inadequate contract, agreement, or billing review process, the OIG may determine it necessary to conduct its own review to determine whether, or the extent to which, Transworld is complying with its obligations under this CIA. Transworld agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents.

H. Confidential Disclosure Program

1. *Reporting System.* Transworld represents that prior to the Effective Date of this CIA, Transworld has implemented a reporting system enabling individuals to disclose any practices or procedures, alleged by an individual to be inappropriate, to an individual who is not in the disclosing individual's direct chain of command (the "Confidential Disclosure Program").

Within 120 days after the Effective Date of this CIA, Transworld shall ensure that its operation of the Confidential Disclosure Program is performed in a manner that allows and encourages individuals to make such disclosures and that emphasizes a non-retribution, non-retaliation policy, and that provides anonymity for confidential disclosures.

2. *Hot Line.* Transworld shall continue to provide for, and make known throughout the organization, a toll-free compliance hot line. Reporting through the hotline shall be available to all directors, officers, employees, contractors, and any other individuals, 24-hours a day, seven days a week, for the purpose of making any disclosures, or asking any questions, regarding Transworld's Corporate Compliance Program, the obligations of this CIA, and the Legal Requirements.

3. *Review of Disclosures.* Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry for every disclosure to ensure that Transworld has obtained all of the information necessary to determine whether an internal review should be conducted or whether the disclosure warrants other appropriate action. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for

taking corrective action, Transworld shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of any investigations related to such disclosures, and any corrective action taken in response to any allegations.

I. Dealing with Ineligible Persons

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* Transworld shall not hire or engage as a contractor any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Transworld shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, Transworld shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Transworld shall review the list annually. In addition, Transworld shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Transworld has notice that an employee or contractor has become an Ineligible Person, Transworld shall remove such person from responsibility for, or involvement with, Transworld's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the services or items rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Transworld has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or

contract, Transworld shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

J. Reporting

1. *Reporting of Overpayments.* If, at any time and including as a result of the Retrospective Claims Reviews, Transworld identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, Transworld shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any overpayments within 30 days of discovering credible evidence of the overpayment and take remedial steps within 60 days of discovering credible evidence of the overpayment (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the payor should be done in accordance with payor policies, including policies regarding treatment of underpayments, although notification of an overpayment to the payor shall include the gross overpayment amount.

2. *Reporting of Material Deficiencies.* If Transworld determines that there is a material deficiency, Transworld shall notify OIG within 30 days of making the determination that the material deficiency exists. The report to OIG shall include the following information:

- a. If the material deficiency results in an overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section H.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - i. the payor's name, address, and contact person where the overpayment was sent; and
 - ii. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid;
- b. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
- c. Transworld's actions to correct the material deficiency; and
- d. any further steps Transworld plans to take to address such material deficiency and prevent it from recurring.

Any report of overpayments to the OIG must include gross overpayment amounts, notwithstanding any underpayments which may exist.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money Transworld has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves:

- a. a substantial overpayment relating to any Federal health care program; or
- b. a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized;

A material deficiency may be the result of an isolated event or a series of occurrences.

5. *Notification of Proceedings.* Within 30 days of discovery, Transworld shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Transworld has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Transworld shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that Transworld purchases or establishes new business units after the Effective Date of this CIA, Transworld shall notify OIG of this fact within 30 days of the date of purchase or establishment. This notification shall include the location of the new operation(s), telephone number, facsimile number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All Covered Persons at such locations shall be subject to the requirements in this CIA that apply to new Covered Persons (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date of this CIA, Transworld shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (the "Implementation Report"). The Implementation Report shall include:

1. the name, address, telephone number and position description of the Compliance Officer required by Section III.A.1;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. a copy of Transworld's Code of Conduct required by Section III.B.1;
4. a copy of the Policies and Procedures required by Section III.B.2;
5. a description of the training programs required by Section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer, after reasonable inquiry and to the best of his or her knowledge, that:
 - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by Section III.C.1; and
 - c. all Covered Persons, Billing Personnel, and Sales Personnel have completed the training and executed the certifications required by Section III.C.
7. a copy of Transworld's policies regarding the Confidential Disclosure Program required by Section III.H;
8. a summary of any personnel actions taken pursuant to Section III.I.; and
9. a list of all of Transworld's locations (including locations and mailing addresses), the corresponding name under which each location is doing business; the corresponding telephone numbers and facsimile numbers, each location's Federal health care program supplier number(s), and the name, address, and telephone number of

the payor (specific contractor) that issued each provider identification number.

B. Annual Reports

Within 90 days of the first, second, third, fourth, and fifth anniversaries of the Effective Date of this CIA, Transworld shall submit to OIG a written report with respect to the status and findings of Transworld's compliance activities over the previous 12-month period ("Annual Reports").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in Section III.A;
2. a certification by the Compliance Officer, after reasonable inquiry and to the best of his or her knowledge, that:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by Section III.C.1;
 - b. all Covered Persons, Billing Personnel, and Sales Personnel have completed the training and executed the certifications required by Section III.C; and
 - c. Transworld has complied with its obligations under the Settlement Agreement not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement) and, if applicable, its obligation to identify and adjust any past charges of unallowable costs;
3. notification of any changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);
4. for the relevant 12-month period covered by the Annual Report: (a) a report on the operation of the coinsurance (co-payment and deductible) collection process; (b) the amounts of coinsurance for Medicare beneficiaries (i) due on all claims (prior to billing), (ii) billed (to insurers and/or beneficiaries), and (iii) collected; and (c) a report summarizing the reasons for uncollected coinsurance amounts and the efforts of Transworld to collect such amounts;

5. a description of each failure of a Commission Sales Employee to meet the standards set forth in Section III.E, a description of Transworld's actions to cure the failure and take remedial action, and a list of all personnel or employment actions taken where a Commission Sales Employee had not cured a failure to meet the standards set forth in Section III.E within 30 days of notification of such failure, as well as a description of each failure to meet the standards set forth in Section III.E that provided the basis for such personnel or employment actions;
6. the identity of the Legal Reviewer and a complete copy of any written reports generated by the Legal Reviewer relating to its review of applicable independent contractor agreements and employment agreements or relationships with Commission Sales Employees, pursuant to the requirements set forth in Section III.F;
7. a complete copy of the Retrospective Claims Review Reports and, unless otherwise directed by OIG, of the Independent Review Organization's reports of findings regarding the Retrospective Claims Reviews, for each product line for each quarter, as well as the identity of the Independent Review Organization(s) retained by Transworld to perform the reviews of Transworld's Retrospective Claims Reviews, pursuant to the requirements set forth in Section III.F;
8. for the first Annual Report only, a complete copy of the Compliance Review Report prepared in accordance with and pursuant to the requirements set forth in Section III.F, as well as the identity of the Independent Review Organization retained by Transworld to perform the Compliance Review;
9. Transworld's response/corrective action plan, if applicable, to any issues raised by the reviews performed or reports generated pursuant to the requirements set forth in Section III.F;
10. a summary of material deficiencies identified and reported throughout the course of the previous twelve (12) months pursuant to III.J and the corrective action plan(s) to address such material deficiencies;
11. a report of the aggregate overpayments that have been identified through Transworld's Compliance Program and returned to the Federal health care programs during the one-year period covered by

the Annual Report, pursuant to Section III.J. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs. This report must include gross overpayment amounts, notwithstanding any underpayments which may exist;

12. a copy of the Confidential Disclosure Log required by Section III.H;
13. a summary of any personnel action (other than hiring) taken by Transworld as a result of the obligations in Section III.I;
14. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Transworld has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to Section III.K. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information; and
15. a description of all changes to the most recently provided list (as updated) of Transworld's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program supplier number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each supplier identification number.

C. Certifications

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) Transworld is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and, upon such inquiry, to the best of his or her knowledge, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone (202) 619-2078
Facsimile (202) 205-0604

Transworld:

Transworld Healthcare, Inc.
11 Skyline Drive
Hawthorne, NY 10532
Attention: Chief Financial Officer
Telephone: (914) 345-8880
Facsimile: (914) 345-8935

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine, subject to any legal privileges, Transworld's books, records, and other documents and supporting materials and/or conduct an onsite review of Transworld's operations for the purpose of verifying and evaluating: (a) Transworld's compliance with the terms of this CIA; and (b) Transworld's compliance with the requirements of the Federal health care programs in which it participates. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Transworld's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Transworld agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. Transworld's employees may elect to be interviewed with or without a representative of Transworld present, or with or without legal counsel.

VIII. Document and Record Retention

Transworld shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, for six (6) years (or longer if otherwise required).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Transworld prior to any release by OIG of information submitted by Transworld pursuant to its obligations under this CIA and identified upon submission by Transworld as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Transworld shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by Transworld of Transworld's attorney-client, attorney work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Transworld's obligation to comply with the provisions of this CIA, *e.g.*, by providing all documents necessary to determine whether Transworld is in compliance with the terms of this CIA.

X. BREACH AND DEFAULT PROVISIONS

Transworld is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Transworld and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days after the Effective Date of this CIA and concluding at the end of the term of this CIA, Transworld fails to have in place any of the following:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. written Code of Conduct;
- d. written Policies and Procedures;

- e. a training program; and
- f. a Confidential Disclosure Program;

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Transworld fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Transworld employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Transworld's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Transworld can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.I) as to the status of the person).

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Transworld fails to grant access) for each day Transworld fails to grant access to the information or documentation as required in Section VII of this CIA.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue 10 days after the date that OIG provides notice to Transworld of the failure to comply) for each day Transworld fails to comply fully and adequately with any obligation of this CIA where the failure to comply does not form the basis for a stipulated penalty under Sections X.A.1-4 above. With respect to the Stipulated Penalty provision described in this Section X.A.5 only, OIG shall not seek a Stipulated Penalty if Transworld demonstrates to OIG's reasonable satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that (i) Transworld has begun to take action to cure the failure to comply, (ii) Transworld is pursuing such action with due diligence, and (iii) Transworld has provided to OIG a reasonable timetable for curing the failure to comply. In its notice to Transworld, OIG shall state the specific grounds for its determination that Transworld has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Transworld has failed to comply with any of the obligations described in Section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Transworld by personal service or certified mail of (a) Transworld's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within 10 days of Transworld's receipt of the Demand Letter, Transworld shall either (a) cure the breach to OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.D. In the event Transworld elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Transworld cures, to OIG's satisfaction, the alleged breach in dispute. Transworld's request of a hearing before an ALJ shall not preclude Transworld's opportunity to cure the alleged breach. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.C.

Transworld's decision to cure any alleged breach shall not be construed as or constitute evidence of an admission of non-compliance under this CIA in any subsequent legal proceeding.

2. *Timely Written Requests for Extensions.* Transworld may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Transworld fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Transworld receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's determination that Transworld has materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in Section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Transworld constitutes an independent basis for Transworld's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Transworld has materially breached this CIA and that exclusion should be imposed, OIG shall notify Transworld by certified mail of (a) Transworld's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

2. *Opportunity to Cure.* Transworld shall have 30 days from Transworld's receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's reasonable satisfaction that:

- a. Transworld is in full compliance with this CIA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 35-day period, but that: (i) Transworld has begun to take action to cure the material breach, (ii) Transworld is pursuing such action with due diligence, and (iii) Transworld has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 30 day period, Transworld fails to satisfy the requirements of Section X.C.2, OIG may exclude Transworld from participation in the Federal health care programs. OIG will notify Transworld in writing of its determination to exclude Transworld (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.D, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Transworld is excluded under the provisions of this CIA, Transworld may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this CIA means:

- a. a failure by Transworld to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in Section III.J;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A of this CIA;

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c. a failure to respond to a duly delivered Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.B above; or

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with Section III.G.

D. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Transworld of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Transworld shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within 150 days of Transworld's receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 30 days of Transworld's receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be (a) whether Transworld was in full and timely compliance with the obligations of this CIA for which OIG demands payment; (b) the period of noncompliance; and (c) with respect to a stipulated penalty authorized under section X.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) Transworld had begun to take action to cure the failure to comply, (ii) Transworld was and is pursuing such action with due diligence, and (iii) Transworld had provided to OIG a reasonable timetable for curing the breach which is being followed. Transworld shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders Transworld to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless Transworld requests review of the ALJ decision by the DAB, in which case the Stipulated Penalties shall become due and payable (20) days after the DAB issues a decision confirming the ALJ's finding.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a

proceeding for exclusion based on a material breach of this CIA shall be (a) whether Transworld was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not have been cured within the 30 day period, but that (i) Transworld had begun to take action to cure the material breach within that period, (ii) Transworld has pursued and is pursuing such action with due diligence, and (iii) Transworld provided to OIG within that period a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. Transworld's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Transworld upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Transworld may request review of the ALJ decision by the DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Transworld and OIG agree as follows:

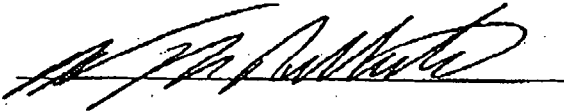
A. This CIA shall be binding upon Transworld and on the successors, assigns, and transferees of Transworld, including any entity surviving a merger with Transworld or created as a result of a consolidation with Transworld;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

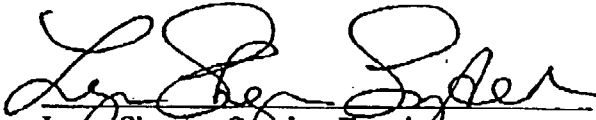
D. The undersigned Transworld signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF TRANSWORLD HEALTHCARE, INC.



Corporate Officer
Transworld Healthcare, Inc.

August 2, 2000
Date



Lynn Shapiro Snyder, Esquire
Epstein, Becker & Green, P.C.
Counsel for Transworld Healthcare, Inc.

August 1, 2000
Date

Carrie Valiant, Esquire
Epstein, Becker & Green, P.C.
Counsel for Transworld Healthcare, Inc.

Date

Corporate Integrity Agreement:
Transworld Healthcare, Inc.




ON BEHALF OF TRANSWORLD HEALTHCARE, INC.

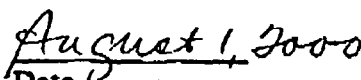
Corporate Officer
Transworld Healthcare, Inc.

Date

Lynn Shapiro Snyder, Esquire
Epstein, Becker & Green, P.C.
Counsel for Transworld Healthcare, Inc.

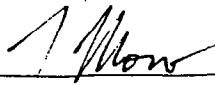
Date


Carrie Valiant, Esquire
Epstein, Becker & Green, P.C.
Counsel for Transworld Healthcare, Inc.


Date



**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

8/4/00
Date